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(71) Applicant: Sherwood Services AG
8200 Schaffhausen (CH)

(72) Inventor: McPherson, James W.
Boulder, Colorado 80301 (US)

(74) Representative: Hoffmann, Klaus
Hoffmann - Eitile
Patent- und Rechtsanwälte
Arabellastrasse 4
D-81925 München (DE)

(54) RF return pad current detection system

(57) The present disclosure provides an electrosurgical return pad current detection system for use in monopolar surgery as well as a method of using the same. The detection system comprises a plurality of conductive pads which include a plurality of conductive elements. The detection system further includes a sensor which

senses the current returning to each conductive pad as well as a comparator which determines the difference in current among a plurality of conductive pads. If the current differential is above or below a prescribed limit, the system will alert the user of potential hazards and/or alter the amount of energy delivered to a surgical device.

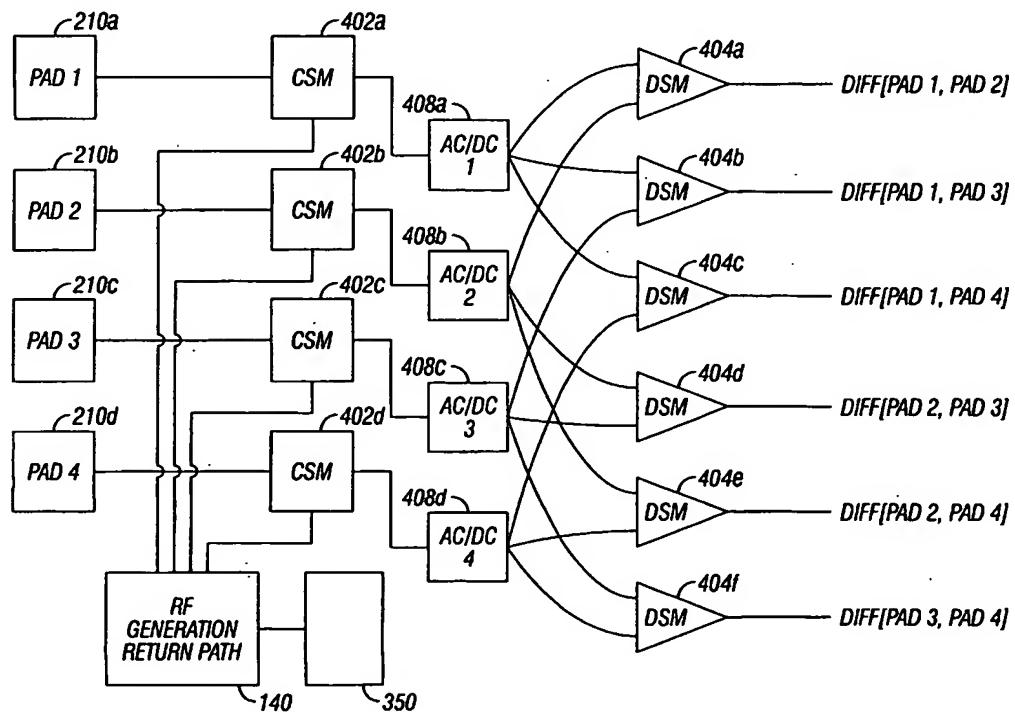


FIG. 5

Description**BACKGROUND*****Technical Field***

[0001] The present disclosure is directed to an electrosurgical apparatus and method, and, is particularly directed to a patient return electrode pad and a method for performing monopolar surgery and RF ablation using the same.

Background

[0002] During electrosurgery, a source or active electrode delivers energy, such as radio frequency energy, from an electrosurgical generator to a patient. A return electrode carries the current back to the electrosurgical generator. In monopolar electrosurgery, the source electrode is typically a hand-held instrument placed by the surgeon at the surgical site and the high current density flow at this electrode creates the desired surgical effect of cutting, ablating and/or coagulating tissue. The patient return electrode is placed at a remote site from the source electrode and is typically in the form of a pad adhesively adhered to the patient.

[0003] The return electrode typically has a relatively large patient contact surface area to minimize heat concentrations at that patient pad site (i.e., the smaller the surface area, the greater the current density and the greater the intensity of the heat.) Hence, the overall area of the return electrode that is adhered to the patient is generally important because it minimizes the chances of current concentrating in any one spot which may cause patient burns. A larger surface contact area is desirable to reduce heat intensity. The size of return electrodes is based on assumptions of the anticipated maximum current during a particular surgical procedure and the duty cycle (i.e., the percentage of time the generator is on) during the procedure. The first types of return electrodes were in the form of large metal plates covered with conductive jelly. Later, adhesive electrodes were developed with a single metal foil covered with conductive jelly or conductive adhesive. However, one problem with these adhesive electrodes was that if a portion peeled from the patient, the contact area of the electrode with the patient decreased, thereby increasing the current density at the adhered portion and, in turn, increasing the heat applied to the tissue. This risked burning the patient in the area under the adhered portion of the return electrode if the tissue was heated beyond the point where normal circulation of blood could cool the skin.

[0004] To address this problem, split return electrodes and hardware circuits, generically called Return Electrode Contact Quality Monitors (RECQMs), were developed. These split electrodes consist of two separate conductive foils arranged as two halves of a single return electrode. The hardware circuit uses an AC signal be-

tween the two electrode halves to measure the impedance therebetween. This impedance measurement is indicative of how well the return electrode is adhered to the patient since the impedance between the two halves

5 is directly related to the area of patient contact. That is, if the electrode begins to peel from the patient, the impedance increases since the contact area of the electrode decreases. Current RECQMs are designed to sense this change in impedance so that when the percentage increase in impedance exceeds a predetermined value or the measured impedance exceeds a threshold level, the electrosurgical generator is shut down to reduce the chances of burning the patient.

[0005] As new surgical and therapeutic RF procedures 15 continue to be developed that utilize higher current and higher duty cycles, increased heating of tissue under the return electrode may occur. Ideally, each conductive pad would receive substantially the same amount of current, therefore reducing the possibility of a pad site burn. However, this is not always possible due to patient size, incorrect placement of pads, differing tissue consistencies, etc. It would therefore be advantageous to design a return electrode pad which has the ability to detect and correct 20 a current imbalance between pads, therefore reducing the likelihood of patient burns.

SUMMARY

[0006] The present disclosure provides an electrosurgical return pad current detection system for use in monopolar surgery. The detection system comprises a plurality of conductive pads which include a plurality of conductive elements. The detection system further includes a plurality of sensors which sense the current returning 30 to each conductive pad as well as a comparator for sensing the difference in current between a plurality of conductive pads.

[0007] The present disclosure may also include an ablation generator which may regulate the amount of power 40 delivered to a surgical device. In operation, the return pad current detection system is placed in contact with the patient. A generator enables the transfer of radio frequency current from an active electrode to at least one of a plurality of conductive elements. The plurality of sensors measures the amount of current returning to each pad. This information is then processed a comparator which detects any possible imbalances in current between the pads. If there is a substantial imbalance the user is warned of such a situation and the generator automatically corrects the imbalances.

[0008] In one embodiment of the present disclosure the current sensor of each conductive pad is a current sense transformer. Alternatively, the current sensor could be, *inter alia*, a non-inductive sense resistor.

[0009] In another embodiment of the present disclosure the comparator is a differential or instrumentation amplifier.

[0010] It is envisioned for the generator to utilize the

information provided by the comparator to alert the user of potential hazardous conditions and to prevent injury. This may be achieved using a variety of differing methods including safety control, neural network, or fuzzy logic algorithms.

[0011] In one embodiment, a full-wave rectifier is connected to the current sensor in order to convert the returning current signal from alternating current to direct current.

[0012] The present disclosure also includes a method for performing monopolar surgery. The method utilizes the return pad current detection system as described above. The method also includes placing the return pad current detection system in contact with a patient; generating electrosurgical energy via an electrosurgical generator; supplying the electrosurgical energy to the patient via an active electrode; measuring the current returning to each conductive pad; detecting imbalances in current by comparing the current returning to one conductive pad with the current returning to each of the remaining pads; warning the user of possible hazardous conditions; and substantially correcting or regulating the imbalances among pads.

[0013] For a better understanding of the present disclosure and to show how it may be carried into effect, reference will now be made by way of example to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The above and other aspects, features, and advantages of the present disclosure will become more apparent in light of the following detailed description when taken in conjunction with the accompanying drawings in which:

FIG. 1 is a schematic illustration of a monopolar electrosurgical system;

FIG. 2 is a plan view of an electrosurgical return electrode according to one embodiment of the present disclosure, illustrating a conductive pad having a grid of conductive elements of substantially equal sizes;

FIG. 3 is a plan view of an electrosurgical return electrode according to another embodiment of the present disclosure, illustrating a conductive pad having a grid of conductive elements of varying sizes;

FIG. 4 is an enlarged schematic cross-sectional view of a portion of the return electrodes; and

FIG. 5 is an electrical schematic of the multiple RF return pad current detection system.

DETAILED DESCRIPTION

[0015] Embodiments of the presently disclosed multi-

ple RF return pad current detection system and method of using the same are described herein with reference to the accompanying drawing figures wherein like reference numerals identify similar or identical elements. In the following description, well-known functions or constructions are not described in detail to avoid obscuring the disclosure in unnecessary detail.

[0016] Referring initially to FIG. 1, a schematic illustration of a monopolar electrosurgical system 100 is shown.

10 The electrosurgical system 100 generally includes a surgical instrument (e.g., electrosurgical pencil, electrical scalpel, or other active electrode) 110, a return electrode 200, a connection device 300 for connecting the return electrode 200 to a generator 120, and a current detection system 400 disposed on or operatively associated with the return electrode 200 (FIG. 4). In FIG. 1, the return electrode 200 is illustrated placed under a patient "P." Electrosurgical energy is supplied to the surgical instrument 110 by the generator 120 via a cable 130 to cut, 15 coagulate, blend, etc. tissue. The return electrode 200 returns energy delivered by the surgical instrument 110 to the patient "P" back to the generator 120 via return path 140.

[0017] The current detection system 400 is in operative engagement with the return electrode 200 and operatively connected to the connection device 300 via a cable 250. The connection device 300 may be operatively connected to the generator 120 (FIG. 1), may be operatively connected to the return electrode 200 (FIGS. 2 and 3), 25 may be disposed between the return electrode 200 and a generator 120 (FIG. 4) or housed within generator 120.

[0018] FIGS. 2, 3 and 4 illustrate various embodiments of the return electrode 200 for use in monopolar electrosurgery. Generally, the return electrode 200 is a conductive pad 210 having a top surface 212 (FIG. 4) and a bottom surface 214 (FIG. 4). The return electrode 200 is designed and configured to receive current during monopolar electrosurgery. While the figures depict the return electrode 200 in a general rectangular shape, it is 30 within the scope of the disclosure for the return electrode 200 to have any regular or irregular shape, such as circular, polygonal, etc.

[0019] As illustrated in FIGS. 2, 3 and 4, the conductive pad 210 is comprised of a plurality of conductive elements 45 (only conductive elements 220a - 220f are labeled for clarity) arranged in a regular or irregular array. Each of the plurality of conductive elements 220 may be equally-sized or differently-sized and may form a grid/array (or be disposed in any other grid-like arrangement) on the conductive pad 210. It is also envisioned and within the scope of the present disclosure for the plurality of conductive elements 220a-220f to be arranged in a spiral or radial orientation (not shown) on the conductive pad 210.

[0020] As illustrated in FIG. 4, current detection system 50 55 400 includes an array of individual current sensors (illustrated as 402a-402f, corresponding to conductive elements 220a - 220f, respectively), which are able to measure the amount of current returning to each pad, e.g.,

210a. The current detection system 400 may be operatively connected to the plurality of conductive elements 220a-f on the top surface 212 or bottom surface 214 (or anywhere therebetween) of conductive pad 210. For example, individual current sensors 402a may be operatively connected to conductive element 220a. Moreover, each current sensor, e.g. 402a may be connected via a common cable 250 to a comparator 404 (see FIG. 5), which may be housed in a multitude of different configurations, including within connection device 300 or generator 120. Alternatively, a series of current detection systems, e.g. 400a, may be connected to a connection device 300 via a respective cable 250a (FIG. 5). In the interest of clarity, each of the possible cable arrangements for cables 250a-d connected to each current detection system 400a-d are not illustrated.

[0021] Generally, the area of the return electrode 200 that is in contact with the patient "P" affects the current density of a signal that heats the patient "P." The smaller the contact area the return electrode pad 210 has with the patient "P," the greater the current density which directly affects tissue heating at the contact site. Conversely, the greater the contact area of the return electrode 200, the smaller the current density and the less heating of tissue at the patient site. As can be appreciated, higher current densities lead to greater heating of tissue and greater probability of patient burn. It is therefore important to either ensure a relatively high amount of contact area between the return electrode pad 210 and the patient "P," or otherwise maintain a relatively low current density on the return electrode pad 210.

[0022] While there are various methods of maintaining a relatively low current density (including, *inter alia*, the use of electrosurgical return electrode monitors (REMs), such as the one described in commonly-owned U.S. Patent No. 6,565,559, the entire contents of which are hereby incorporated by reference herein), the present disclosure ensures low current density at the patient site by sensing the amount of current returning to each of the plurality of conductive elements 220a-f of the return electrode 200 and adjusting the energy accordingly to reduce current densities at the patient site.

[0023] More particularly, the current detection system 400 of the present disclosure has the ability to measure the amount of current returning to each conductive element 220a-220f. Each conductive element 220a-f is connected to the connection device 300 and may be activated and/or deactivated (or adjusted) as needed. For example, if a conductive element (e.g., 220a) along the perimeter of the conductive pad 210 becomes relatively hot, that conductive element 220a may be disconnected from the connection device 300, deactivated or adjusted to receive a lower amount of energy. In this example, the conductive element 220a would not receive any more energy or receive a reduced amount of energy and the current level in the area of the pad contacting the conductive element 220a would dissipate. It is envisioned and within the scope of the present disclosure for the

disconnection/reconnection, deactivation/reactivation of the conductive elements 220a-f to occur automatically as a result of an algorithm (or the like) provided in the electrosurgical generator 120.

- 5 [0024] It is also envisioned and within the scope of the present disclosure for a disconnected conductive element, e.g., 220a, to be reconnected to the connection device 300 when the current level of a particular conductive element or particular area of the pad 210 in contact with the corresponding current detection system 400 decreases. Utilizing these features, the current levels of the return electrode 200 can be relatively consistent throughout the entire surface thereof, thus reducing the possibility of "hot spots" and patient burns. For example, the grid-like arrangement of the pad 210 makes it easier for the generator 120 to identify and adjust current levels at different pad 210 locations depending upon the current build-up possibly reducing the likelihood of patient burns.
- 10 [0025] Referring now to FIG. 5, the current detection systems 400 may be operatively associated with a plurality of pads 210a-d which operatively connect to generator 140. One or more algorithms controls the electrical energy associated with each pad to reduce patient burn. Current detection system 400 includes a sensing device
- 15 402a for sensing the current to each conductive pad 210a-210d as well as at least one a comparator 404a-404f which senses the difference in current between the plurality of conductive pads 210a-210d. Current detection system 400 is connected to a plurality of conductive elements 220a-220f (see FIGS. 2 and 3) on each pad 210a-210d and may be located in a variety of different areas including, on conductive pads 210a-210d, inside connection device 300, or within generator 120. Other locations for current detection system 400 are envisioned
- 20 and are within the scope of the present disclosure.
- 25 [0026] The current sensor(s), e.g., 402a may take a number of different forms including, but not limited to, open loop sensors, closed loop sensors, digital current sensors, Hall-effect devices or a current sense transformer (not shown), the operation of which will be described hereinbelow. In use, the return current for each conductive pad e.g., 210a, is passed through a toroidal magnetic, which forms a 1:N current sense transformer comprised of 1 turn from the return wire and N turns of the toroidal core. The waveform representing the current can be converted to a voltage waveform by placing a resistor between the terminations of the toroidal core turns. This voltage waveform is substantially sinusoidal in nature and may require further modification. An AC/DC converter circuit, e.g. 408a, may be utilized to substantially convert the alternating current signal of the return current into a direct current signal. This eliminates any phase or frequency modulation that could lead to inaccuracies in measurement. This DC response is representative of the
- 30 amount of RF current flowing through each conductive pad 210. AC/DC converter circuit may be operatively associated with each respective sensor 402a-402d.
- 35 [0027] Once the DC response of each conductive pad

210a is obtained, the signal may then be fed into a comparator e.g., 404a. Each comparator 404a receives two distinct DC inputs, each from a separate conductive pad, e.g., 210a, 210b. It is envisioned that one possible type of comparator 404a is an instrumentation amplifier. Instrumentation amplifier receives a DC input from two different conductive pads 210a, 210b and calculates the current differential between the two. This difference is then multiplied by the gain of comparator or instrumentation amplifier 404a in order to obtain a scaled representation of imbalances between any two of the pads e.g. 210a, 210b. Ideally, the current differential would be negligible with each pad receiving the same amount of return current. However, if a substantial imbalance is present, a warning is provided via a warning device(audible or visual) or safety control algorithms which are utilized to mitigate pad site burns which will be described hereinbelow.

[0028] Generator 120 may contain, *inter alia*, embedded software. It is envisioned that this embedded software may be utilized to develop safety control algorithms or similar warning mechanisms. Using the information provided by comparator(s) 404a-404d, generator 120 may be able to modulate the amount of power delivered to each conductive pad 210a-210d therefore minimizing the chances of pad site burns. Moreover, this information may also be processed using a variety of different techniques, including but not limited to, neural networks or fuzzy logic algorithms.

[0029] It should be noted that a current sense transformer may be replaced with any current measuring device such as a non-inductive sense resistor. Similarly, comparator or instrumentation amplifier could be replaced with a number of different devices including, but not limited to, differential amplifiers. Moreover, AC/DC converter circuit(s) 408a-408d may take on a number of different forms such as a full-wave rectifier circuit.

[0030] During electrosurgical use of the return electrode pad 210, portions of the perimeter of the return electrode pad 210 may become hot at a faster rate than the center of the return electrode pad 210. In such a situation, as seen in FIG. 3, it may be desirable to have the conductive elements 220a-220f near the perimeter of the return electrode pad 210 be smaller than the remaining conductive elements 220g-220i. Monitoring the returning current levels of each conductive pad(s) 210a-210d and each conductive element 220a-220i of each pad 210a-210d would allow greater control of the overall temperature of the portions of the patient "P" in contact with the entire return electrode pad or pads. Thus, the return electrode pad 210, as a whole, would be able to receive a greater amount of current, as some new procedures necessitate. Moreover, and as illustrated in FIG. 5, a plurality of pads 210a-210d may be utilized each with a plurality of conductive elements 220a-220i which all may be individually regulated or controlled to reduce patient burns.

[0031] To further limit the possibility of patient burns,

it is envisioned that an adhesive layer 500 may be disposed on the return electrode 200 about the periphery of pad 210, as illustrated in FIGS. 2 and 3. The adhesive layer 500 may be conductive and may be made from

5 materials that include, but are not limited to, a polyhesive adhesive; a Z axis adhesive; or a water-insoluble, hydrophilic, pressure-sensitive adhesive and is desirably made of a polyhesive adhesive. Such materials are described in U.S. Patent Nos. 4,699,146 and 4,750,482, 10 the entire contents of each of which are herein incorporated by reference. A function of the adhesive layer 500 is to ensure an optimal surface contact area between the return electrode 200 and the patient "P" thus limiting the possibility of a patient burn.

15 [0032] It is envisioned that the return electrode(s) 200 may be entirely disposable, entirely re-usable, or a combination thereof. In one embodiment, the conductive elements 220 are re-usable, while the adhesive layer 500 is disposable. Other combinations of disposable/re-usable 20 portions of the return electrode 200 are envisioned and within the scope of the present disclosure.

[0033] It is envisioned that a multiplexer 260 may be employed to control switching of the plurality of conductive elements 220a-220f, as illustrated in Fig. 4. For ex-

25 ample, it is envisioned that the multiplexer 260 may be configured to regulate the current in any fashion by switching "on" and "off" various amounts of the plurality of conductive elements 220a-220f. While the multiplexer 260 is illustrated between the generator 120 and the connection device 300, other locations for the multiplexer 260 are envisioned and within the scope of the present disclosure.

[0034] The present disclosure also includes a method for performing monopolar surgery. The method utilizes 30 one or more return pads operatively associated to one another which form a current detection system 400 as described above. The method also includes placing one or more return pads of the current detection system 400 in contact with a patient; generating electrosurgical energy via an electrosurgical generator 120; supplying the electrosurgical energy to the patient via a surgical instrument 110; measuring the current returning to each conductive pad 210a-210d; detecting imbalances in current by comparing the current returning to one conductive pad 40 210a with the current returning to each of the remaining pads 210b-210d; warning the user of possible hazardous conditions; and providing a means for substantially correcting the imbalances.

[0035] While several embodiments of the disclosure 50 have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, 55 but merely as exemplifications of preferred embodiments. For example, it is envisioned for the return electrode 200 to be at least partially coated with a positive temperature coefficient (PTC) material to help distribute

the heat across the return electrode 200, as described in commonly-owned U.S. Provisional Patent Application Serial No. 60/666,798, the entire contents of which are hereby incorporated by reference herein.

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Claims

1. A return pad current detection system for use in monopolar surgery, comprising:

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a plurality of conductive pads, wherein each conductive pad includes a plurality of conductive elements; a plurality of sensors operatively connected to the plurality of conductive pads which sense current returning to each pad; and a comparator which determines the difference in current among the plurality of conductive pads, said comparator operatively connected to a warning device which warns a user if the current differential among pads is above or below a certain predetermined limit.

2. System according to claim 1, further comprising an ablation generator, wherein the ablation generator regulates the amount of power delivered to a surgical device based upon the current sensed from each pad.

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3. System according to claim 2, wherein the ablation generator utilizes information provided by at least one comparator to substantially correct a current differential among pads.

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4. System according to claim 3, wherein the information provided to the ablation generator is processed by neural networks or fuzzy logic algorithms.

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5. System according to any one of the preceding claims, wherein the sensor is at least one of a current sense transformer and a Hall-Effect device.

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6. System according to any one of the preceding claims, wherein the comparator is at least one of a non-inductive sense resistor, a differential amplifier and an instrumentation amplifier.

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7. A return pad current detection system for use in monopolar surgery, comprising:

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an electrosurgical generator capable of generating electrical current; a plurality of conductive pads, wherein each conductive pad includes a plurality of conductive elements, the conductive pad defining a perimeter; a plurality of sensors operatively connected to

the plurality of conductive pads which sense current returning to each pad; a plurality of ac to dc converters producing an output, wherein each converter is connected to one of the plurality of sensors of each pad; and a plurality of differential sensing devices, wherein each differential sensing device is dimensioned to receive the output of at least two distinct ac to dc converters and each differential sensing device's output corresponds to a signal representative of the current differential among at least two pads.

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8. System according to claim 7, wherein the electrosurgical generator is constructed and arranged to provide a warning if the current differential among pads is above or below a certain limit.

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9. System according to claim 7 or 8, wherein the electrosurgical generator is constructed and arranged to modulate the amount of power delivered if the current differential among pads is above or below a certain limit.

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10. System according to claim 7, 8 or 9, wherein the sensing device is at least one of a current-sense transformer and non-inductive sense resistor.

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11. System according to any one of claims 7 to 10, further comprising a full-wave rectifier connected to the current sensing means, wherein the full-wave rectifier substantially converts a signal from alternating current to direct current.

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12. System according to any one of claims 7 to 11, wherein the differential sensing device is at least one of a differential amplifier and an instrumentation amplifier.

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13. System according to any one of claims 7 to 12, wherein the ac to dc converter is a full-wave rectifier.

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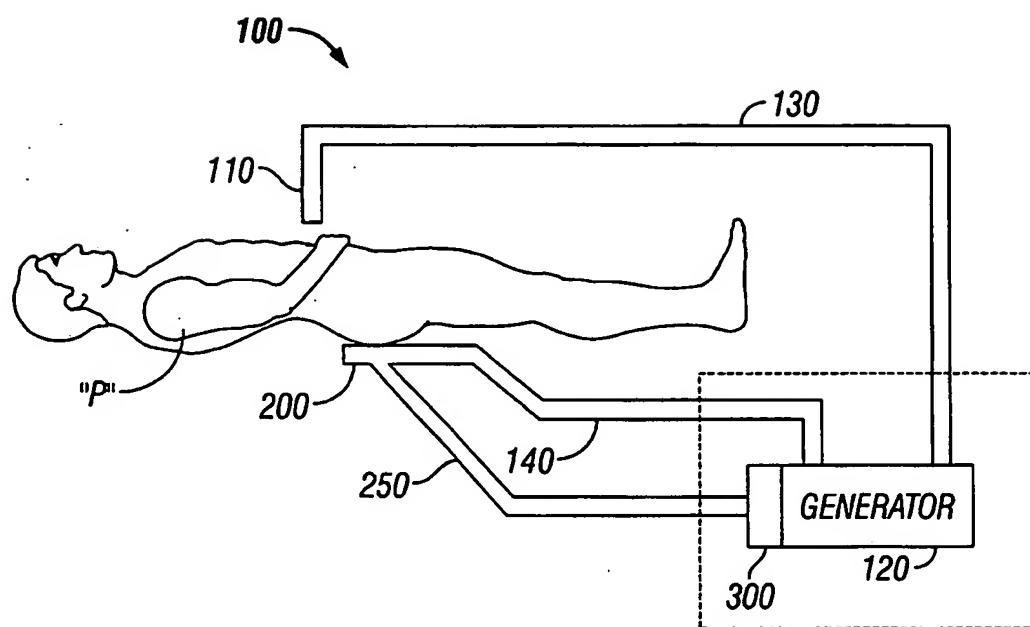


FIG. 1

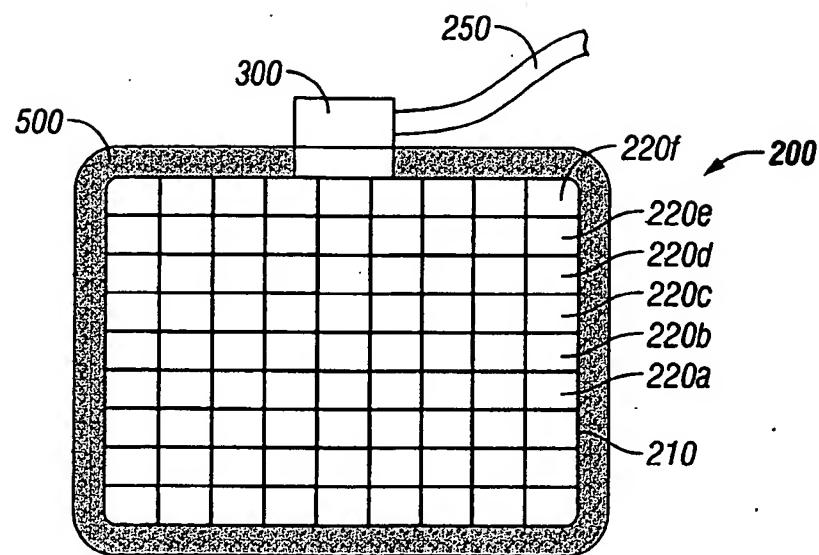


FIG. 2

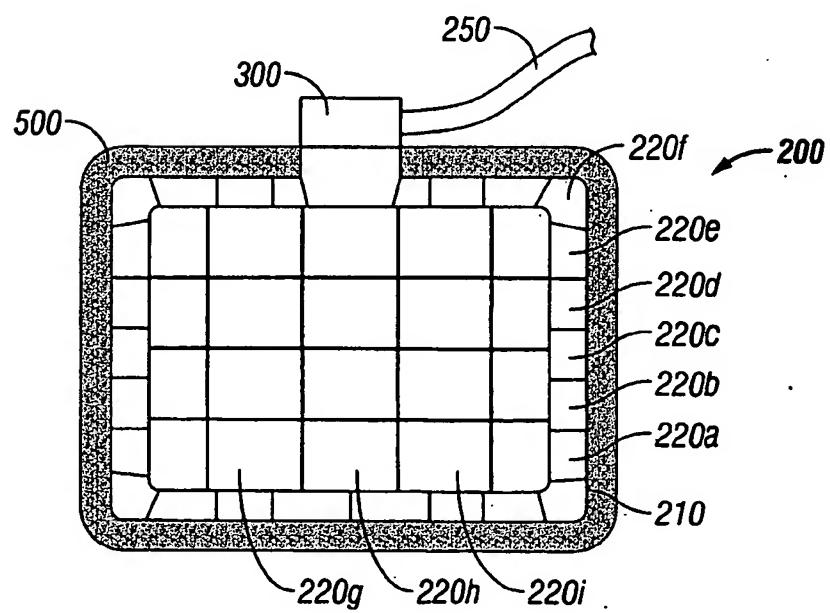


FIG. 3

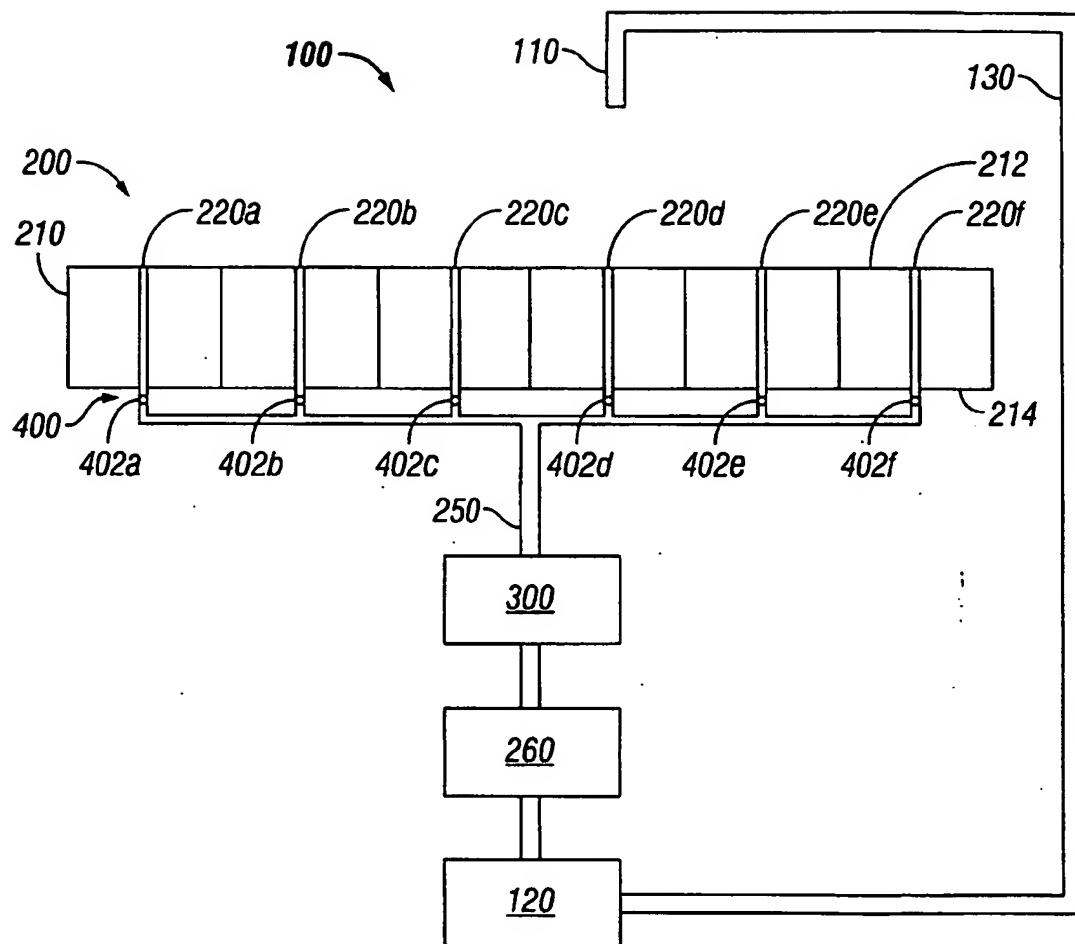


FIG. 4

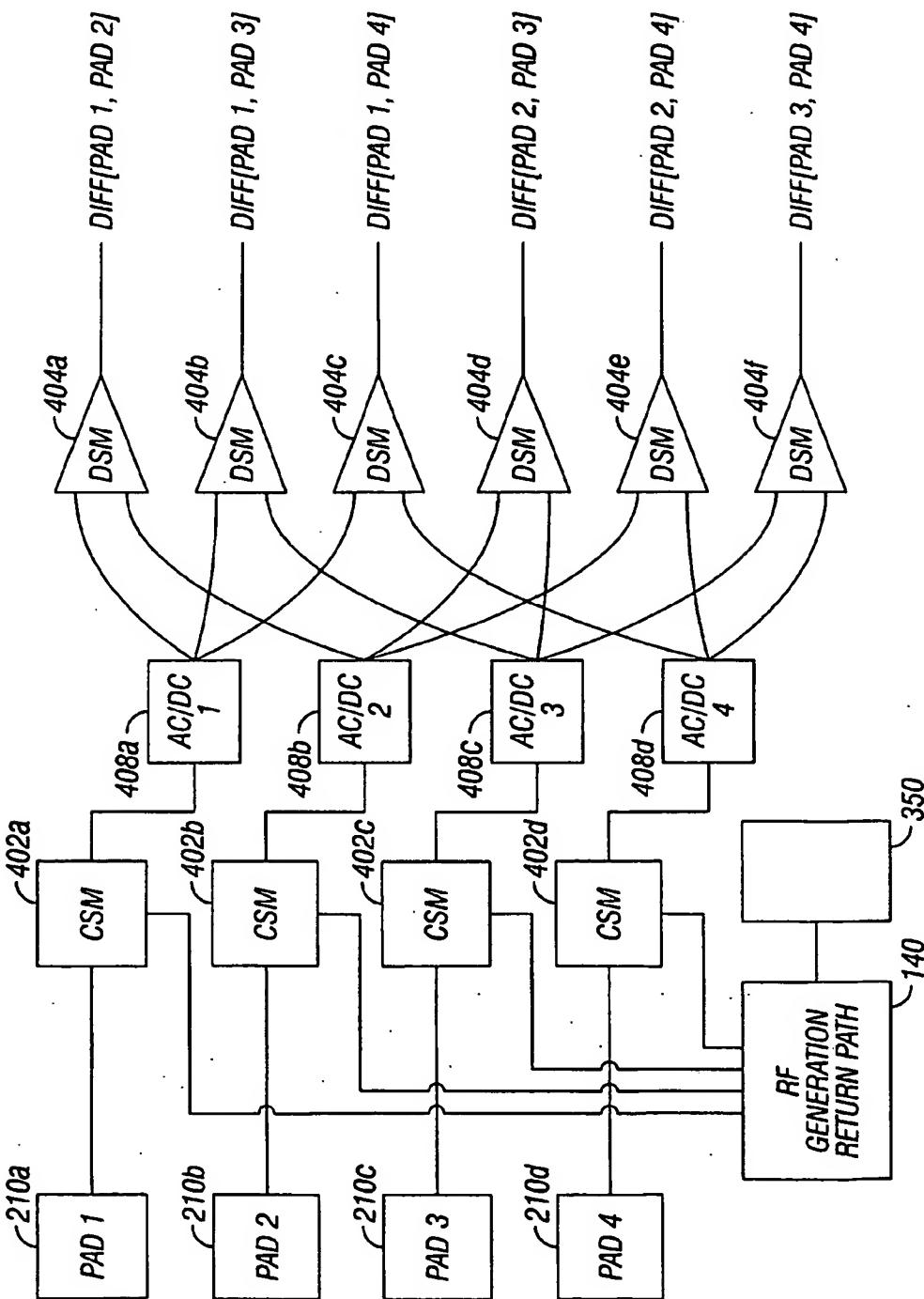


FIG. 5

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 6565559 B [0022]
- US 4699146 A [0031]
- US 4750482 A [0031]
- US 666798 P [0035]